



# 2009 NCI SBIR INVESTOR FORUM

**NOVEMBER 5, 2009** 

8:00 AM - 6:00 PM

### **BOSTON UNIVERSITY TRUSTEE BALLROOM**

1 Silber Way, 9<sup>th</sup> Floor Boston, MA, USA 02115

NATIONAL CANCER INSTITUTE

SMALL BUSINESS INNOVATION RESEARCH (SBIR) AND
SMALL BUSINESS TECHNOLOGY TRANSFER (STTR) PROGRAMS

**BOSTON UNIVERSITY** 

### **LETTER FROM NCI SBIR**

Welcome to the inaugural National Cancer Institute (NCI) Small Business Innovation Research (SBIR) Investor Forum. Thank you for joining us. I hope that today will be a valuable opportunity for you to learn more about the most promising small businesses developing new and innovative technologies for the treatment and diagnosis of cancer. These companies were chosen from a highly competitive field of applicants based on their strength of research, product development, and market potential.

The NCI SBIR & STTR program invests over \$100 million annually into a portfolio that includes over 300 projects. As one of the largest sources of early-stage, non-dilutive technology financing in the United States, the NCI SBIR Program has long been an important source of capital for small businesses to push promising technologies through development and commercialization.

Today's Investor Forum represents the latest in a number of new and exciting steps implemented by the NCI SBIR Development Center to further help companies drive the commercialization of novel technologies and products. Today will also provide a chance for investors and strategic partners to learn about the NCI SBIR Bridge award. This award, a \$3 million funding opportunity, represents a new way for both the NCI and potential investors to work together to leverage their investments while investing in the most promising companies.

It is no secret that in today's economic climate, early-stage life sciences companies face a very daunting challenge in accessing the capital needed to advance their discoveries. We are pleased to be able to play an active role in bridging connections between these small businesses and potential investors and strategic partners that could ultimately fulfill the mission of NCI to reduce the burden of cancer.

We have designed today's agenda to allow ample time for you to interact with these companies and learn about their products and investment opportunities. The NCI SBIR Development Center staff will also be available today and beyond this meeting to discuss the many ways the NCI can work with your organization to support the commercialization of emerging cancer technologies.

Throughout the day, I encourage you to participate by asking questions, sharing thoughts, networking with others, and learning more about these innovative companies which we believe are poised to play an important role in the fight against cancer.

Michael Weingarten

Director

**NCI SBIR & STTR Programs** 

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### **LETTER FROM BOSTON UNIVERSITY**

On behalf of all of us at Boston University, welcome to the conference! We hope you enjoy the presentations and your time on our campus.

The commercialization of new technologies to diagnose and treat cancer is a major step in beating this disease. Many of you at this conference have most likely been touched by cancer, either personally, through a family member, or through a close acquaintance. The reality is that the treatments that cancer victims are receiving today most likely started in early stage research-based companies. While it takes many years to develop viable commercial interventions to achieve clinical use, we can't afford to miss early golden opportunities to improve our weapons in fighting this devastating ailment. Enter the NCI SBIR & STTR Programs and the NCI SBIR Bridge award.

As an entrepreneur and investor, I have always been a bit skeptical of government funded programs aimed at promoting commercial activity. However, in 2008 I was introduced to Michael Weingarten and his team who run the SBIR/STTR programs at SBIR Development Center at NCI. Over the past several years this group has funded numerous outstanding technologies that would not be available to patients today without this NCI support. It is simply one of the most impactful ways I know of to expedite the translation from basic research to marketable product.

I know it is easy to lose sight of the "prize" when working on complex research activities or with programs that seem years away from completion. However, the stories you will hear today from the investigators and entrepreneurs illustrate the passion and dedication of these pioneers toward reaching the prize—beating cancer. With help from NCI, I am confident they will do it.

Enjoy your day, and again, welcome to Boston University.

Sincerely,

N. Stephen Ober, MD, MBA Executive Director, New Ventures



### **NCI SBIR OVERVIEW**

## LEADING SMALL BUSINESS INNOVATION AND COMMERCIALIZATION IN THE FIGHT AGAINST CANCER

### **Overview of the NCI SBIR & STTR Programs**

Small businesses are a national resource for the development of innovative technologies and a mainstay of the American economy. The Small Business Innovation Research (SBIR) and Small Business Technology Transfer (STTR) Programs were created by the U.S. Congress to strengthen the role of small, innovative companies in federally supported research and development. At the National Cancer Institute (NCI), these programs seek small business participation in the development and commercialization of technologies that will help in the fight against cancer. Specifically, the NCI SBIR & STTR Programs seek to support research and development of anticancer agents, biomarkers, informatics, medical devices, cancer imaging, nanotechnology, proteomics, pharmacodynamics, as well as many other areas of interest. Entrepreneurs and small businesses are encouraged to explore grant and contract funding opportunities to support work in these areas.

The NCI SBIR & STTR Programs serve as one of the largest sources of early-stage technology financing in the United States. Through these programs, small businesses can receive seed capital to push promising technologies through development and toward commercialization. In addition, there are several other reasons why SBIR & STTR funding may be right for your business:

- SBIR & STTR awards provide recognition, verification, and visibility
- SBIR & STTR funding can be a leveraging tool to help attract additional funding from other third-party investors
- Awards are not loans; no repayment is required
- SBIR & STTR funding is non-dilutive capital (i.e., an award does not impact the company's stock or shares in any way)
- Intellectual property rights to technologies developed under these programs are retained by the small business concern

### **SBIR: Small Business Innovation Research**

The NCI SBIR Program funds early-stage research and development within small businesses.

To participate in the NCI SBIR Program:

- The Small Business Concern (SBC) must be an organized for-profit business of 500 employees or fewer (including affiliates), located in the United States
- The SBC must be:
  - At least 51 percent U.S.-owned by individuals and independently operated

#### OR

- At least 51 percent owned and controlled by another for-profit business concern that is at least 51 percent U.S.-owned by individuals and independently operated
- The Principal Investigator's primary employment must be with the SBC at the time of award and for the duration of the project period

### STTR: Small Business Technology Transfer

The NCI STTR Program is similar in structure to SBIR with the exception of funding cooperative research and development projects involving a small business and a research institution (i.e., college or university, federally-funded center, non-profit research institution). The purpose of STTR is to create an effective vehicle for moving ideas from our nation's research institutions to the commercial market.

To participate in the NCI STTR Program:

- The SBC must meet the same size and ownership guidelines as for the SBIR Program
- The company must be engaged in a formal cooperative research and development effort with a U.S. research institution (i.e., college or university, federally-funded research and development center, or non-profit research institution)
- A minimum of 40 percent of the work must be done by the small business and a minimum of 30 percent of the work must be done by the research institution
- The Principal Investigator's primary employment may be with either the SBC or the research institution

### PROGRAM GOALS

To help achieve the NCI's mission, the SBIR & STTR Programs act as NCI's catalyst of innovation for developing and commercializing novel technologies and products to prevent, diagnose, and treat cancer.

The goals of the NCI SBIR & STTR Programs are to:

- Stimulate technological innovation
- Increase private-sector commercialization of federal research and development
- Increase small business participation in federally funded research and development
- Foster participation by minority and disadvantaged companies in technological innovation

### **HOW TO APPLY**

The NCI SBIR & STTR Programs are your entryway to federally funded cancer research. Organizations must first apply for a Phase I award. If Phase I proves successful, the company may apply for a two-year Phase II award to further develop the concept, usually to the prototype stage. Funding is awarded competitively. Proposals are judged on the basis of scientific, technical, and commercial merit.

Dedicated NCI program staff members are available to answer questions about the NCI SBIR & STTR Programs and to help meet your research program needs. For further information regarding program eligibility, limitations, definitions, and other resources, please visit our Web site at: sbir.cancer.gov.

### THREE-PHASE PROGRAM

### The NCI SBIR & STTR Programs Are Structured in Three Phases

**Phase I.** The objective of the Phase I project is to test the technical merit and feasibility of a particular concept. Phase I support is normally \$100,000 provided over a period of six months for SBIR and one year for STTR. However, with proper justification, applicants may propose longer periods of time and

greater amounts of funds necessary to establish the technical merit and feasibility of the proposed project.

**Phase II.** The objective of the Phase II project is to continue the research and development efforts initiated in Phase I. Only previously-funded Phase I awardees are eligible to compete for a Phase II award. Phase II awards are normally \$750,000 over two years. However, with proper justification, applicants may propose longer periods of time and greater amounts of funds necessary for completion of the project.

Bridge Award. The objective of the new SBIR Phase II Bridge Award is to address the funding gap known as the "Valley of Death" between the end of the SBIR Phase II award and commercialization, and encourage partnerships between NIH's SBIR Phase II awardees and third-party investors and/or strategic partners. Up to \$1 million in total costs per year and project periods up to three years (a total of \$3 million over three years) may be requested from the NCI.

**Phase III.** The objective in Phase III is for the small business concern to pursue with non-SBIR & STTR funds the commercialization objectives resulting from the Phase I/II research and development activities.

### CONTACT INFORMATION

### Small Business Innovation Research Development Center National Institutes of Health

National Cancer Institute Building 31, Room 10A19 31 Center Drive, MSC 2580 Bethesda, Maryland 20892-2580 sbir.cancer.gov

Main phone number: 301-594-7709 Email address: ncisbir@mail.nih.gov

### **SBIR FUNDING OPPORTUNITIES**

### NCI SBIR AND STTR PROGRAMS FUNDING IS AVAILABLE THROUGH THE FOLLOWING VEHICLES:

### **Contract Topics**

#### Application typically due in November

The NCI SBIR offers contract funding opportunities once a year in a range of novel technology areas to help successfully finance and advance innovations towards commercialization. There are currently \$12 million available for 23 contract topic funding opportunities for small businesses to support the research and development of anti-cancer agents, biomarkers, health information technology, nanotechnology, proteomics, pharmacodynamic assays, and many other areas of interest to the NCI.

Applications are due November 9.

### **Phase II Bridge Award**

### New announcement coming soon

NCI's newest funding initiative, the SBIR Phase II Bridge Award, is specifically designed to augment previously funded NIH-wide SBIR Phase II projects that require additional funding in order to achieve key technical and regulatory milestones along the path toward commercialization.

#### **Grants and Omnibus Solicitation**

### Application typically due April, August, and December

Funding opportunities are intended for U.S. small businesses that have the research capabilities and technological expertise to contribute to the research and development missions of the awarding components identified in the Omnibus solicitation and are encouraged to apply.

### Innovative Molecular Analysis Technologies (IMAT)

### Please check on the sbir.cancer.gov site for new funding announcements

Funding in this category encourages the inception, development, integration, and application of novel and emerging technologies in support of cancer research, treatment, diagnosis, and prevention. Specific themes include research centered on the inception and early stage development of new technologies for cancer research, evaluating technologies that are ready for initial clinical or laboratory application in cancer research, and developing of novel sample preparation technologies that are suitable for molecular analyses of cancer cells and their host environments.

For more information about the National Institutes of Health SBIR and STTR funding opportunities and to sign-up to receive e-mail notifications when new funding announcements are released, please visit: http://sbir.cancer.gov.

### **SBIR CONTACT INFORMATION**



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### **NCI SBIR INVESTOR FORUM COMMITTEE**

### THE NCI SBIR DEVELOPMENT CENTER WOULD LIKE TO THANK THE FOLLOWING FOR THEIR HELP:

Abi Barrow The Massachusetts Technology Transfer

Center

Richard Anders Still River Funds and Mass Medical

Angels

Carl Berke Partners Research Ventures and

Licensing and Medical Angels

Bruce Booth Atlas Ventures

Anupendra Sharma Siemens Ventures

Mark Benedyk The Pfizer Incubator

Robert Sarisky Johnson & Johnson Pharmaceutical

Research and Development, L.L.C.

eRED Program

N. Stephen Ober Boston University

Al Hawkins Boston University

**Ashley Stevens** Boston University

Rick Clark Boston University

**Hong Xu** Boston University

Chelsea Hewitt San Jose BioCenter

Sandy Miller The Kauffman Foundation

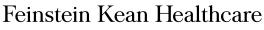
### THE NCI SBIR FORUM COLLABORATORS:











An Ogilvy PR Worldwide Company











### NCI SBIR INVESTOR FORUM AGENDA

12:45 p.m. – 1:00 p.m. 1:00 p.m. – 1:15 p.m.

8:00 a.m. – 8:25 a.m.	Registration and Continental Breakfast				
8:25 a.m. – 8:30 a.m.	Welcome/Agenda Review				
	Speaker: N. Stephen Ober, M.D., M.B.A, Boston University Office of Technology				
	Development, Executive Director, New Ventures				
8:30 p.m. – 8:40 p.m.	Welcome from Boston University School of Medicine				
	Speaker: Douglas Faller, M.D., Ph.D., Director, Boston University Cancer Center				
8:40 a.m. – 9:00 a.m.	Welcome from NCI and Overview of the SBIR Phase II Bridge Award				
	Speaker: Michael Weingarten, Director, NCI SBIR Development Center				
Company Presentations					
9:00 a.m. – 9:15 a.m.	Lpath, Inc. (Therapeutics)				
9:15 a.m. – 9:30 a.m.	Syntrix Biosystems, Inc. (Therapeutics)				
9:30 a.m. – 9:45 a.m.	Altor BioScience Corporation (Therapeutics/Biologics)				
9:45 a.m. – 10:00 a.m.	Progenra, Inc. (Therapeutics/In vitro Diagnostics)				
10:00 a.m. – 10:15 a.m.	Zacharon Pharmaceuticals, Inc. (Therapeutics/In vitro Diagnostics)				
10:15 a.m. – 10:30 a.m.	20/20 GeneSystems, Inc. (In vitro Diagnostics)				
10:30 a.m. – 11:15 a.m.	Prockout Mactings				
10.50 d.111. – 11. 15 d.111.	Breakout Meetings				
Company Presentations					
11:15 a.m. – 11:30 a.m.	Advanced Cell Diagnostics, Inc. (In vitro Diagnostics)				
11:30 a.m. – 11:45 a.m.	MagArray, Inc. (In vitro Diagnostics/ResearchTools)				
11:45 a.m. – 12:00 p.m.	Koning Corporation (Devices)				
12:00 p.m. – 12:15 p.m.	PathfinderTherapeutics, Inc. (Devices)				
12:15 p.m. – 12:30 p.m.	GuidedTherapeutics, Inc. (Devices)				
12:30 p.m. – 12:45 p.m.	Visualase, Inc. (Devices)				

Optimum Technologies, Inc. (Devices)

Intra-Medical Imaging, L.L.C. (Devices)

### NCI SBIR INVESTOR FORUM AGENDA

1:15 p.m. – 1:45 p.m.	Luncheon			
1:45 p.m. – 2:15 p.m.	Luncheon Session Keynote			
	Speaker: Scott Sarazen, Global Life Sciences Markets Leader, Ernst & Young, L.L.P.			
2:15 p.m.– 3:00 p.m.	Breakout Meetings			
3:00 p.m. – 3:45 p.m.	Panel Discussion: Harnessing the Bridge Award to Maximize Investments and			
	Catalyze Commercialization - Successful Partnerships Between NCI SBIR			
	Phase II Bridge Awardees and Investors			
	Speakers:			
	Robert Hofmeister, Senior Director EMD Serono Research Institute			
	<ul> <li>Robert Kruger, President of OptoSonics</li> </ul>			
	<ul> <li>David Steinberg, CEO of Enlight Biosciences</li> </ul>			
	<ul> <li>Roger Sabbadini, Vice President and CSO of Lpath, Inc.</li> </ul>			
	Michael Weingarten, Director, NCI SBIR Development Center			
3:45 p.m. – 4:00 p.m.	Closing Remarks			

**Networking Reception** 

4:00 p.m. – 6:00 p.m.

### **SPEAKER BIOGRAPHIES**



N. Stephen Ober, M.D., M.B.A, Boston University Office of Technology Development, Executive Director, New Ventures

Dr. Ober is Executive Director of New Ventures in Boston University's Office of Technology Development. New

Ventures was founded in 2006 to support BU faculty and students establish new companies based on BU research and technologies. In addition to supporting spin-off activities. New Ventures has responsibility for managing BU's business incubator, running the venture capital fund, and managing a pre-seed investment program (Launch Awards). Dr. Ober is also director of the five year MD/MBA dual degree program, a collaborative program between Boston University Schools of Medicine and Management. Prior to joining BU in 2004, Dr. Ober was co-founder and president of BG-Medicine, Inc., a biotechnology company that developed and applied a unique "systems biology" approach to drug discovery and development. Prior to BG-Medicine, Dr. Ober was president and chief executive officer of Synergy Health Care, a successful health information and data management company. Synergy was founded by Dr. Ober in 1995 and was acquired by ENVOY Corp. in 1998. In March 1999, ENVOY was acquired by Quintiles Transnational, the world's largest Clinical Research Organization. Prior to Synergy, Dr. Ober spent five years as executive vice president and corporate medical director of Private Health Care Systems (now part of Multiplan, Inc.), one of the largest national managed care companies in the country.

Dr. Ober received his B.A. and M.D. degrees from Boston University, his clinical training in surgery and orthopedic surgery from University of California San Diego, and his MBA from the Harvard Graduate School of Business.



Douglas Faller, M.D., Ph.D., Director, Boston University Cancer Center

Douglas V. Faller, M.D., Ph.D., is Director of the Cancer Center at Boston University School of Medicine. He is also Vice-Chairman of the Department of Medicine and Professor of Medicine, Biochemistry,

Pediatrics, Microbiology, Pathology and Laboratory Medicine.

Dr. Faller is an experienced translational cancer research investigator and holds a number of Phase I and Phase II INDs for clinical testing of new cancer therapeutics developed out of his laboratory. Dr. Faller is the recipient of multiple awards and honors. He has multiple patents or patent applications for cancer therapeutics or diagnostics and ongoing multi-center investigator-initiated trials, has over 300 research publications, and has been the recipient of over 60 federal or foundation research grants. His current research support includes multiple grants from NCI, NHLBI, STTR awards, and the Department of Defense, as well as multiple foundations, including the V-Foundation and the Leukemia-Lymphoma Society.

Dr. Faller received his M.D. from Harvard Medical School and his Ph.D. from the Massachusetts Institute of Technology. He received his post-graduate residency at the University of California San Francisco and subspecialty training in adult and pediatric Hematology and Oncology at Boston Children's Hospital, Brigham and Women's Hospital, the Dana-Farber Cancer Institute, and Harvard Medical School, where he was previously on the faculty in the Departments of Medicine and Pediatrics.



Michael Weingarten, Director, NCI SBIR Development Center

Michael Weingarten is the Director for the Small Business Innovation Research (SBIR) Development Center at the National Cancer Institute, one of 27 Institutes of the National Institutes of Health (NIH) in

Bethesda, MD. In this role, Mr. Weingarten manages all aspects of the NCI SBIR and STTR programs including a portfolio of over \$100M in grants and contracts annually. The SBIR and STTR programs are NCI's engine of innovation for developing and commercializing novel technologies and products to prevent, diagnose, and treat cancer.

In his current role, Mr. Weingarten led a team that developed a set of key recommendations for optimizing the performance of the NCI SBIR program at the NIH. Those recommendations included the establishment of an SBIR Development Center to manage the NCI SBIR program. This Center is staffed with talented leaders from both industry and the NIH who have expertise in the development and commercialization of technology in the cancer field to optimize the returns the NCI achieves through this program.

### **SPEAKER BIOGRAPHIES**

Mr. Weingarten also created and designed a brand new funding program for the NIH known as the SBIR Phase II Bridge Award, which more than triples the amount of funding available to applicants through the NCI SBIR Program. The Phase II Bridge Award will help small businesses "bridge" the funding gap known as the "Valley of Death," that currently exists between the end of the SBIR Phase II award and the next round of financing needed to advance a promising cancer therapy or imaging technology. The new Phase II Bridge Award is specifically designed to augment previously funded NIH-wide SBIR Phase II projects in the areas of cancer therapies and cancer imaging that require additional funding in order to achieve key technical and regulatory milestones along the path toward commercialization. This new award incentivizes partnerships between NIH's SBIR Phase II awardees and third-party investors and/or strategic partners.

Prior to joining the NIH, Mr. Weingarten was the Manager of Partnership Development activities for NASA's Technology Transfer program which included the SBIR program. In his 12 years with NASA Headquarters in Washington, D.C., Mr. Weingarten played a major role in the creation and design of NASA's Technology Transfer program – a network of 10 NASA research centers and six regional technology transfer centers. Mr. Weingarten has a bachelor's degree in political science from Northwestern University, Chicago, III., and a master's degree in political science from Columbia University in New York City.



### Scott Sarazen, Global Life Sciences Markets Leader, Ernst & Young, LLP

Scott serves in the role of Markets Leader within Ernst & Young's Global Life Sciences Center. In this role, Scott is responsible for all aspects of the firm's global marketing, communication and go-

to-market strategies for the pharmaceutical, biotechnology and medtech industries. Mr. Sarazen and the marketing team serve as the primary conduit between the firm and the life science industries for the purposes of tracking the changing landscape of these dynamic sectors and communicating EY's proven value proposition.

Mr. Sarazen has enjoyed over 20 years of experience working directly and indirectly in the life science industries. Prior to joining EY in 2006, Scott's career has included roles in biopharmaceutical facilities design, strategic operations and business development in positions as: Senior Vice

President of Corporate Development at Straumann, North America and Director of Global Planning and Development at Genzyme Corporation. Scott has also served in public economic development roles, advocating for the expansion of the biomedical industries, as the Senior Vice President for Life Sciences with MassDevelopment for the Commonwealth of Massachusetts and as a special consultant to the Chief Economic Development Officer for the City of Boston.

Mr. Sarazen holds a Bachelors of Science in Engineering from Worcester Polytechnic Institute and a Masters of Science in Management from Lesley University.

In addition to other affiliations, Scott serves on the: Advisory Board of the Harvard-MIT Division of Health Sciences and Technology (HST); Board of Trustees for the KIPP Academy in Lynn, MA; the Advisory Board for the City of Boston's Life-Tech Initiative; Advisory Board for Boston World Partnerships; and on the Economic Development Committee at the Massachusetts Biotechnology Council.



### Robert Kruger, President, OptoSonics

Dr. Robert Kruger received his Ph.D. in physics from the University of Wisconsin-Madison in 1978 and has been working as an imaging scientist ever since. He has served on the faculties of the

University of Utah and Indiana University School of Medicine, where he was professor of Radiology until 2003. He founded OptoSonics in 1994, where he and co-workers pioneered a new medical imaging paradigm called "thermoacoustic computed tomography". He is author of over 130 publications on this and other topics and has been issued 25 U.S. and foreign patents.



David Steinberg, Chief Executive Officer, Enlight Biosciences

David Steinberg is a Partner at PureTech Ventures, a Boston-based venture creation firm. As a member of PureTech, Mr. Steinberg has been a co-founder of multiple biotech and life science

start-ups, including Enlight Biosciences and Endra Inc. as founding CEO and board member. Previously, he served as Chief Business Officer of portfolio company Follica, Inc., and

### **SPEAKER BIOGRAPHIES**

VP of Operations for portfolio company Satori Pharmaceuticals. Prior to joining PureTech, he was a strategy consultant with the Boston Consulting Group and Vertex Partners, focusing on R&D and product strategy and strategic alliances for Fortune 500 pharmaceutical and biotechnology firms. Mr. Steinberg also worked as a research associate in Procter and Gamble Pharmaceuticals' R&D organization. Mr. Steinberg received his BA in Biology with distinction from Cornell University and graduated with high honors from the University of Chicago Graduate School of Business with an M.B.A. in strategy and finance.



### Roger Sabbadini, Vice President and Chief Scientific Officer, Lpath, Inc.

Dr. Sabbadini has been a professor of Biology at San Diego State University for over 31 years and is now Professor of Biology Emeritus. He is the founder three biotechnology companies incubated

out of San Diego State University, including Lpath, Inc., Vaxiion Therapeutics and Mpex BioSciences. Dr. Sabbadini is focused on developing novel antibody-based therapeutics against bioactive lipids such as sphingolipids which can become dysfunctional and directly contribute to the pathophysiology of cancer, inflammation, angiogenesis and cardiovascular diseases. Dr. Sabbadini is also interested in bacterial minicells as vectors for DNA and protein antigen delivery for therapeutic vaccine development and for targeted drug delivery and diagnostic applications in cancer. Dr. Sabbadini received his Ph.D. from the University of California, Davis and was a Fellow of the Muscular Dystrophy Association before taking a faculty position at SDSU. He has received several academic awards including the Outstanding Faculty Alumni Association Award; SDSU College of Sciences; California State University System-wide CSUPERB outstanding faculty research award: Wang Family Excellence Award for distinguished scholarship at SDSU and the Presidential Award as one of 25 Most Influential Members of the SDSU Community. He has received several federal grants, most recently a SBIR Phase II Bridge Award from the National Cancer Institute.



### Robert Hofmeister, Ph.D.

Dr. Robert Hofmeister is Senior Director in the Therapeutic Area Oncology at EMD Serono Research Institute in Rockland, MA. Dr. Hofmeister began his career with the company in 2005 in the emerging oncology drug discovery branch, where he was

instrumental for building up a therapeutic antibody platform. Following the formation of EMD Serono in 2007, he took over as Global Head of Oncology-Target Research. In this role, Dr. Hofmeister is responsible for novel therapeutic concepts, target validation and biomarker research.

Dr. Hofmeister received his Ph.D. degree at the University of Regensburg in Germany, where he worked on cytokine signaling. After completing his post-doc in 1999 at the NCI in Frederick, MD, Dr. Hofmeister moved to Munich, Germany, to join Micromet AG. It was here that Dr. Hofmeister started working in the field of cancer biology and bispecific antibodies recruiting T cells for the elimination of tumor cells.

### PRESENTING COMPANY OVERVIEWS



20/20 GeneSystems, Inc. www.2020gene.com 9430 Key West Ave., Suite 100 Rockville, MD 20850

Jonathan Cohen
President & CEO
Telephone: 240-453-6343
Jcohen@2020gene.com

10:15 a.m. – 10:30 a.m. *In vitro* Diagnostics

20/20 GeneSystems develops and commercializes innovative, proprietary diagnostics tests that aid in the fight against cancer. Our present focus is on tests for lung cancer that fall into two categories:

Early detection of lung cancer: 20/20 is developing a blood test for the early detection of lung cancer in parallel with Ortho Clinical Diagnostics ("OCD") (a Johnson & Johnson company) who licensed rights to the technology from 20/20 (co-exclusive). This product will be used for screening smokers and former smokers to identify very early signs of cancer. (A related product for the early detection of head and neck cancer is also in development.)

Personalized medicine for lung cancer: Our patented platform technology for measuring biomarkers in tumors was awarded over \$2.5 million in government funding in 2008. The technology is now being used by groups at the NCl and leading cancer centers to develop tests to predict responses to several new targeted therapies for lung cancer.

Market opportunity / Competitive advantage: 20/20's patented platform technology supports numerous companion diagnostics each with revenue potential exceeding \$100 million. Development of two such products is now underway. The primary competitive advantage of this technology is its ability to simultaneously identify 10 or more biomarkers from a single

tissue section without grinding it up and loosing morphology. Thus, core needle biopsies (small amounts of tissue) can be assessed for their anticipated response to several different targeted therapies, each of which targets a distinct signaling pathway.

20/20 also is the sole owner of a separate biodefense "spin-off" company called 20/20 BioResponse. That company sells a patented kit to emergency responders for screening suspicious powders BioCheck (www.BioCheckInfo.com ). This profitable business unit experienced 15% sales growth in 2008 with potential revenue growth of up to 50% growth in 2009 with additional capitalization.



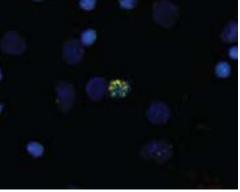
Advanced Cell Diagnostics, Inc www.acdbio.com 26229 Eden Landing Road Hayward, CA 94545 Yuling Luo, Ph.D.
Founder, President & CEO
Telephone: 510-576-8800
ext. 101
vluo@acdbio.com

11:15 a.m. – 11:30 a.m. *In vitro* Diagnostics

Advanced Cell Diagnostics, Inc. (ACD) is the world leader in *in situ* RNA detection. Its proprietary RNAscope<sup>TM</sup> technology is the first multiplex fluorescent and chromogenic *in situ* hybridization platform capable of detecting and quantifying RNA biomarkers at single molecule sensitivity.

Based in the heart of Silicon Valley, ACD was founded and managed by experienced entrepreneurs in the life science industry, who previously founded Panomics, a life science research tool company. Panomics was acquired by Affymetrix in 2008 for \$73 million.

ACD started and was initially funded by two government grants in 2006. Supported in part by a SBIR grant from NCI, ACD has since completed the development of its RNAscope<sup>™</sup> technology and is developing a number of diagnostic products for cancer management. Its major product development effort is focused on the detection and molecular characterization of circulating tumor cells (CTCs) in blood.



A CTC detected Using RNAscope™

Another product would assist the selection of adjuvant therapy for early stage breast cancer patients by in situ detection of RNA biomarkers in FFPE tissue sections. ACD has started early phase clinical studies for these products.

ACD's products are molecular diagnostic tests for personalized cancer treatment, which is one of the fastest growing market sectors representing the future of cancer management. The CTC detection product, in particular, has enormous market potential because not only can each cancer patient be tested multiple times during different stages of cancer progression but also the same approach is applicable to almost all forms of cancer. With more than 10 million cancer patients in US, the potential total market size for CTC detection products is estimated to be well over \$10B.

ACD's RNAscope™ is currently the only effective technology platform capable of robust RNA detection in situ, which unlocks the full potential of RNA biomarkers for clinical diagnostic applications. Compared to existing IHC technology for protein marker detection, RNAscope™ is much more sensitive, specific with higher multiplexing capability. Thus the diagnostic assays based on RNAscope™ can detect diseases earlier, are more robust, precise and information rich. From a business perspective, ACD enjoys an "unfair" competitive advantage as assay conditions for different RNA markers are substantially uniform. This enables ACD to develop products for different applications guickly with minimum development risk.

ACD applies the power of RNAscope™ to CTC detection, which enables its products to not only identify CTCs at higher sensitivity and reliability but also to simultaneously analyze their functional characteristics at molecular level. Such a molecular analysis capability is critically important to cancer management but

less attainable with other CTC detection technologies.

In addition to its ongoing efforts to develop proprietary diagnostic tests for cancer management, ACD also establishes partnerships with pharmaceutical and biotechnology companies to validate biomarkers for targeted therapy and to codevelop companion diagnostics.

ACD received its Series A financing of \$5.4 million from Morningside Ventures in 2008 and is expected to raise Series B in 2010. Series B funding will be used to conduct clinical trials and to obtain regulatory approval for the commercial launch of its first diagnostic test.

Altor Bioscience Corporation Dean Taylor, Ph.D. www.altorbioscience.com **2810 North Commerce Parkway** Miramar, FL 33025

**Chief Business Development Officer** Telephone: 954-443-8600 ext. 832 deantaylor@altorbioscience.com

### **NCI SBIR Bridge awardee**

9:30 a.m. - 9:45 a.m. **Therapeutics/Biologics** 

Altor BioScience Corporation ("Altor" or the "Company") is a privately held, venture-backed, development-stage company engaged in the discovery and development of high-value, targeted immunotherapeutic agents for the treatment of cancer, viral infection and inflammatory diseases. The Company was formed in 2002 by Hing C. Wong, Ph.D., as a spin-off from Sunol Molecular Corporation ("Sunol"), which in turn was spun-out in 1996 from Baxter International. The Company is located in Miramar, Florida, has 21 employees and currently has three products in mid and late phases of clinical development.

Altor is utilizing its novel STAR™ (Soluble T-cell Antigen Receptor) platform technology to capture the precise, disease-targeting properties of T-cell receptors in creating next-generation therapeutic and diagnostic molecules. These innovative molecules promise to enhance the efficacy and reduce the toxicity of existing drugs by

STAR\*\*-Ck STAR\*\*-IgG1 STAR\*\*-Rx

STAR\*\*-Ck STAR\*\*-IgG1 STAR\*\*-Rx

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Activity Immune stimulation

Product ALT-801 ALT-802 Targeted

Candidates ALT-803 Nanoparticles

a cell-specific set of MHC-peptide antigens for T-cell surveillance. Every T-cell produces a TCR with unique and specific binding properties, providing the immune system with the potential to selectively target many different disease antigens, including antigens derived from intracellular protein targets. Altor has captured this potential with the development of its STAR™ (Soluble

targeting a wide range of tumor and viral antigens.

T-cell Antigen Receptor) molecules, to guide therapeutic drugs directly to the sites of disease where they will be most effective. This approach overcomes a major shortcoming of monoclonal antibodies, which mainly target cell-surface proteins but have enjoyed enormous success for treating cancer with 2008 annual sales exceeding \$15 billion.

Products: ALT-801, Altor's lead product for cancer, is a T-cell receptor-targeted immunotherapeutic that recently concluded a Phase I/Ila clinical trial in patients with metastatic malignancies. A Phase II trial against metastatic melanoma will be initiated in late 2009. A second product, an antibody-based Tissue Factor antagonist, is in a multi-center, placebo controlled, randomized Phase II trial for Acute Respiratory Distress Syndrome and Acute Lung Injury, a life-threatening systemic inflammatory disease. These development efforts have been supported by more than \$5.5 MM in SBIR awards from NIH, with an additional \$3 MM Bridge grant from NCI awarded in September 2009. The Company's third product, an antibody that prevents and treats staphylococcal infections in premature neonates, out-licensed to Biosynexus, is in a Phase III registration trial.

Technology: Altor has developed the means for producing biologically active, soluble TCR molecules in a single-chain format (scTCRs). The resulting scTCR or STAR™ molecules retain the TCRs' ability to specifically recognize novel antigen targets on virus-infected or cancerous cells, including intracellular antigens. Altor's unique proprietary platform provides the means to further increase the binding affinity and stability of the STAR™ molecules for commercialization. Moreover, fusion of scTCR to an effector molecule, drug, or drug carrier does not interfere with MHC-restricted, peptide-specific TCR binding activity. The simplicity of this one-step production process results in scTCR fusions with the effector molecule covalently bound, eliminating the need for chemical cross linking. Altor's technology is protected by a broad, integrated

**Background:** In the human immune response, when the T-cell receptors (TCRs), on the surface of T-cells recognize and bind to a tumor or virally infected cell, the T-cells become "activated" and initiate immune responses that eliminate the diseased

Diseased cell

patent portfolio that includes 30 issued U.S. & foreign patents and 57 pending patent applications.

cells. TCRs do not recognize full-length tumor or viral protein, but instead recognize protein fragments (or peptide antigens produced by protease processing), presented on membrane receptors, known as the major histocompatibility complex (MHC) molecules. Through this antigen-presenting pathway, each cell in the body is able to display

Market: Alt ALT-801, util to target IL-tumors. Proform of IL-2

STAR\*\* molecules target disease-specific antigens.

Market: Altor's lead STAR product, ALT-801, utilizes a p53-specific scTCR to target IL-2 to the site of human tumors. Proleukin®, a recombinant form of IL-2, is an approved treatment for advanced metastatic renal cell carcinoma and metastatic melanoma despite significant toxicities. Alter believes a less-toxic version of IL-2 could provide an opportunity to treat a much larger population of patients with renal cell carcinoma and melanoma. In Altor's recently concluded Phase I/IIa trial, ALT-801 also provides clinical benefits to patients with prostate, head and neck and neuroendocrine cancer. An estimated 330,000 HLA-A2+ cancer patients would benefit from Altor's STAR therapeutic candidates representing a market potential estimated at \$10 B.

\_Guided

Guided Therapeutics, Inc. www.guidedinc.com 4955 Avalon Ridge Parkway; Suite 300 Norcross, GA 30071 Mark Faupel, Ph.D.
President and CEO
Telephone: 770-242-8723 ext 303
mfaupel@guidedinc.com

NCI SBIR Bridge awardee 12:15 p.m. – 12:30 p.m.

**Devices** 

Guided Therapeutics, Inc. (Pink Sheets: GTHP) is a development stage company dedicated to early detection of disease that leads

to cervical cancer in a rapid and painless test. The technology is designed to quickly eliminate false positive Pap and HPV results and discover cervical disease missed by existing tests. Our device, the LightTouch™ is a class III device and will require PreMarket Approval (PMA) by the FDA. Unlike Pap and HPV tests, the device does not require a painful tissue sample and results are known immediately. The annual market opportunity



is estimated by the company at over \$1 billion.

Operating as SpectRx, Inc., the company has previously developed and marketed the BiliChek®, a non-invasive, painless monitor for infant jaundice. The BiliChek product line was sold to Respironics in March, 2003. We are an FDA registered, ISO-13485:2003 certified designer and manufacturer of non-invasive diagnostic instruments. Our Quality System has been audited by the FDA and by several of our development partners for compliance with FDA part 820 and ISO-13485:2003. It was also audited by ETL-Semko division of the Intertek Group (http://www.intertek-etlsemko.com) on an annual basis, for compliance with the ISO 13485:2003 standard.

Guided Therapeutics has significant experience in commercializing non-invasive diagnostic technologies. The management team of CEO Mark Faupel, Ph.D., Senior VP of Engineering Richard Fowler and VP of R&D Shabbir Bambot, Ph.D., have over 50 years of combined experience in the medical device field and have over 30 issued U.S. patents and numerous regulatory filings for novel technology in cancer detection and biophotonics. Beginning with our BiliChek infant jaundice monitor where we licensed the technology from the University of Texas M. D. Anderson Cancer Center and following product development, engineering and clinical testing prepared and filed a 510(k) submission for the initial claims. We subsequently filed for expanded claims for use of the product for monitoring during phototherapy after conducting additional clinical trials. In addition to US regulatory approval via the FDA,

the BiliChek has been approved and is currently available for sale in over 60 countries, including the European Union, Japan, and much of South America. BiliChek sales began in 1998 and have been steadily growing. SpectRx has also prepared and filed a PMA application with its partner Roche Diagnostics for a diabetes-screening product that has not yet gone to market.



**IntraMedical Imaging, LLC** www.intra-medical.com 12340 Santa Monica Blvd... **Suite 227** Los Angeles, CA 90025

Farhad Daghighian, Ph.D. President Telephone: 310-826-9834

fd@intra-medical.com

1:00 p.m. – 1:15 p.m. **Devices** 

IMI has been in business for 11 years and has successfully introduced advanced products for surgical oncology. It develops and markets molecular imaging devices for the surgical detection of lymph nodes and the differentiation of cancer from normal tissue.

### Management:

Farhad Daghighian, Ph.D.: President and Chief Scientist – 11 Years with IMI: After attaining his Ph.D. in high-energy physics at UC Irvine, he worked as a postdoctoral scholar at the UCLA's Nuclear Medicine laboratory. After 2 years he joined Memorial Sloan-Kettering Cancer Center. For the following 9 years, he continued pioneering the development of a number of intraoperative nuclear medicine instruments. In 1998, he left New York to establish IntraMedical Imaging LLC in Los Angeles.

Terry Groome, MBA: Vice President, Marketing and Sales- 6 Years with IMI: Has worked in established corporations and startups alike in capacities that include CEO, marketing, and sales. Terry has a BA from the University of Pennsylvania, as well as an MRA.

Mike Loloyan, Ph.D.: Chief Operating Officer - 5 Years with IMI: Ph.D. in Computer & Imaging Sciences, he has been an assistant professor at UCLA radiology department.

Barry Leon, MBA, CPA: Chief Financial Officer – 11 Years with IMI: Is partner with ABL Ventures, that has progressively invested in IMI until it became profitable.

#### **Current Products:**

- 1- Node Seeker®. Radio-isotope guided sentinel node biopsy to determine the stage of cancers
- 2- PET-Probes®. Radio-isotope guided identification of cancer tissue using F-18 FDG.

#### Past milestones:

- Five years of sustainability, due to revenues from the Node Seeker® and PET Probe® line of products.
- Multiple research grants from the National Cancer Institute and US Army.
- Multiple issued patents protecting current and future products
- FDA clearance, ISO-13485 certification, and CE mark
- Exclusive distribution agreement with GE Healthcare in Europe, Middle East, Africa, and Asia

### **New Products in Development:**

Our Phase-II NCI-funded technology is for the Marginator™ Beta Camera. The principle behind the Beta Camera is based on the detection of positrons or electrons that are emitted from certain isotopes. These emissions are collectively called "beta rays". Beta rays have short ranges in tissue; a hand-held radiation detector that is selectively sensitive to beta rays would therefore

> be immune from the effect of the background and can identify small residual radio-active tissue on or

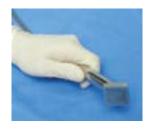
near the surface.

Stage of Development of the Marginator™: The patent for the beta camera is pending. The first prototype has been tested successfully in the laboratory and the testing on surgical samples has started with good results.

Clinical Trials: In addition to this phase-II grant, NCI has granted supplemental money to support a multicenter clinical trial of the Marginator™, at Memorial Sloan Kettering (prostate and GI), Cornell (prostate), Michigan (prostate), John Wayne Cancer Institute



Node Seeker



Marginator™

(breast), Roswell Park Cancer Center (lung), Brigham Women's (brain), and the University of Miami (breast).

IMI has other novel products in various stages of development, such as a position-tracked intra-operative gamma ray scanner, a biopsy needle incorporating a radiation detector for improved guidance, and a portable PET scanner for use during surgery. Impact on Cancer Patients by Addressing the Unmet Need for Complete Excision of Tumor:

Breast Cancer: Breast cancer usually recurs in the breast because the original primary tumor was not completely resected and the remaining cells were not destroyed by adjuvant radiation or systemic therapy. The ability to intra-operatively detect the presence of cancer at the margins of resection within the lumpectomy bed would enable the surgeon to successfully complete the lumpectomy by resecting all involved tissue in one operation. This would avoid a second operation in thousands of women annually.

**Current Methods:** Lumpectomy specimen and several biopsy samples from the cavity are examined by pathologist. These methods suffer from under-sampling, also the results are available after the surgery is over , requiring re-operation in 20 - 40% of patients.

Our Solution: The patient is injected by FDG one hour prior to surgery. Fluorine-18 labeled deoxyglucose is commonly used as a contrast for PET scans. FDG is FDA approved and is universally accepted for having high uptake in aggressive breast cancer tissue. The Marginator™ will be used after the bulk of the tumor is removed to scan the remaining cavity for any leftover cancerous tissues. Positrons emitted from 18F in FDG guide the Marginator™ beta camera to detect residual tumor cells at the margin.

**Prostate cancer:** Annually, surgical treatment is offered to over 70,000 men. Radical prostatectomy involves removal of the prostate, seminal vesicles, surrounding fascia and often regional lymph nodes. This is often associated with postoperative impotence and sometimes residual cancer around the nerves (positive margins). The incidence of positive surgical margins

in patients who have RRP for clinically localized prostate cancer has ranged from 14% to 46%. Cancer in the surgical margin has been shown to be a significant independent adverse factor associated with a greater risk of disease recurrence, local disease recurrence in the prostatic fossa, and systemic progression with death from prostate cancer.

**Current Method:** Positive margins are found postoperatively by the pathologist when cancer is detected at the surface of removed tissue.

**Our Solution:** Hand-held as well as laparoscopic beta cameras will come to contact with the resected cavity and scan for cancer cells.

### Potential Benefits of Application of the Marginator™ Beta Camera:

- Sparing breast cancer patients the pain and emotional trauma of another operation or mastectomy.
- Sparing patients the trauma of loss of urine control or sexual performance in the case of prostate cancer.
- Saving the national health care system money on repeated procedures and morbidity.
- Improving patient care by enhancing surgical outcomes in melanoma, breast, colorectal, lung, brain, ovarian, and prostate cancer.



Koning www.koningcorporation.com 150 Lucius Gordon Drive, Suite 112 West Henrietta, New York 14586

John H. Neugebauer General Manager for US Operations Telephone: 585-214-2459 john.n@koningcorporation.com

**NCI SBIR Bridge awardee** 

11:45 a.m. – 12:00 p.m.

**Devices** 

Koning Corporation is a medical imaging company developing advanced imaging systems that combine the advantages of Digital X-ray and Computed Tomography called Cone Beam CT (CBCT). Producing true isotropic, high spatial resolution images, CBCT scanners can be tailored to specific rather than general applications and have the potential to be faster, smaller and less expensive to own and operate compared to current technology. The Company's first product, Koning Breast CT (KBCT) is a dedicated Cone Beam CT scanner producing thin multi slice and 3D images of the breast tissue for improved detection and diagnosis of breast cancer compared to mammography which is a limited 2D imaging technique.

Breast cancer is the most frequently diagnosed cancer in women, accounting for 32% of cancer occurrence. It is the second leading cause of cancer death among all women and the leading cause of death in females 40-59 years of age. At this time breast cancer can not be prevented, therefore early detection when it is most treatable and associated with an increased survival rate is critical.

Mammography is the current standard of care for early detection. When an abnormality is detected at screening mammography, the patient undergoes diagnostic workup. The

workup includes additional mammographic views, spot views, and magnification views, which in total are referred to as a diagnostic mammography exam. Between 2 to 11 additional views are common. These additional diagnostic views can be non-conclusive as they are restricted by mammography's known limitations. Also, radiation dose to the patient can be substantial as more views are taken. In addition to superior clinical performance over diagnostic mammography, KBCT offers the following competitive advantages:

- Isotropic Resolution
- Full 3d Visualization of the Entire Breast
- Ultra Thin Slice Data in Any Plane
- 90 Second Image Reconstruction
- 3D -Add-on Biopsy Device
- HIS, RIS, and PACS Connectivity
- Internet Access to Images and Patient Data

The Company was established in 2002 as a Delaware "C" Corporation and is registered with the Food and Drug Administration (FDA) as a medical device establishment. It was founded on extensive scientific research on CBCT funded by \$8.3 million in grants from NIH and conducted at the University of Rochester Medical Center (URMC). Koning's founder and President, Ruola Ning PhD, a Professor of Imaging Sciences, Biomedical and Computer Engineering at URMC, is a renowned scientist and a leading authority on Cone Beam CT. He and his team have published over 35 papers on CBCT and his research has resulted in nine US patents licensed exclusively by URMC to Koning Corporation on a worldwide basis.



John Neugebauer is Koning Corporation's General Manager for U.S. Operations. Serving in key positions at leading medical imaging companies to include Philips, CGR, Lorad and Fischer Imaging; he has over 25 years of experience and business leadership in bringing breast imaging products/ technologies to market. During his career, he has also guided "start up" companies with breast imaging devices through FDA approval

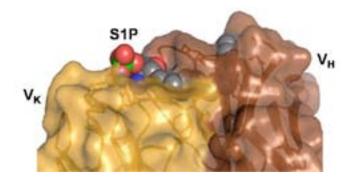
Lpath

Lpath, Inc. www.lpath.com 6335 Ferris Square, Suite A San Diego, CA 92121 Roger A. Sabbadini, Ph.D. Vice President and Chief Scientific Officer Telephone: 858-678-0800 rsabbadini@lpath.com

### **NCI SBIR Bridge awardee**

9:00 a.m. – 9:15 a.m. Therapeutics

San Diego-based Lpath is the category leader in lipidomics-based therapeutics, an emerging field of medicine that targets bioactive signaling lipids for treating a wide range of human disease. Lpath's ImmuneY2™ drug-discovery engine has the unique ability to generate therapeutic antibodies that bind to and inhibit bioactive lipids that contribute to disease, thereby opening up an entire universe of opportunity in drug discovery. Lpath has developed a humanized mAb directed against an important tumor growth-like factor, Sphingosine-1-Phosphate (S1P). We believe that this antibody can be effective in reducing



tumor cell proliferation and protection from apoptosis, tumor-associated angiogenesis, metastatic potential and resistance to chemotherapeutic agents.

The first mAb used in the clinic for the treatment of cancer was Rituxin (Rituximab) which was launched in 1997. Since then it has reached sales in excess of \$2.5 billion per year and has demonstrated the utility of biospecific mAb as therapeutic agents. Not surprisingly, 17 other mAb have since been approved for marketing, including 7 that are prescribed for cancer. The success for these products, as well as the reduced time to develop mAb has made mAb therapeutic the second largest category of drug candidates behind small molecules. Further, the exquisite specificity of antibodies as compared to small molecule therapeutics has proven to be a major advantage both in term of efficacy and toxicity.

S1P is a novel target for the treatment of cancer. Cancer cells exploit the sphingolipid rheostat by promoting conditions that favor the production of S1P release into the extracellular compartment. The ability of cancer cells to release S1P into the tumor microenvironment promotes the infiltration of platelets, fibroblasts, mast cells and neutrophils resulting in an inflammatory response. The infiltrating cells promote further release of S1P into the tumor microenvironment with the resulting manifestation of tumorigenic and pro-angiogenic effects of S1P. Targeting S1P with Lpath's mAb approach is a potential new way to attack cancer. The company is currently advancing three drug candidates, two of which--ASONEP™ for cancer and iSONEP™ for AMD--are in late-Phase 1 clinical trials. For ASONEP, Lpath has joined with international drug giant Merck-Serono under a worldwide exclusive license and development partnership.

Lpath's evolution from a start-up incubated in an academic lab to a publicly-traded entity with an already established management team, complete with a scientific advisory board and two clinical advisory boards, provides evidence that we can handle the ever-changing management needs of a growing biotech company.



MagArray, Inc. www.magarray.com 1230 Bordeaux Dr Sunnyvale, CA 94089 Dr. Shan Wang
Co-Founder, Director, and
Chief Scientist
Telephone: 650-823-7906
shan.x.wang@magarray.com

11:30 a.m. – 11:45 a.m. In vitro Diagnostics/Research Tools

MagArray Inc. is a start-up company spun out of Stanford University to commercialize the magnetic biochip technology developed under Federal funding. All the founders participated in the original biomolecular assay development program focused on labeling target molecules with magnetic nanoparticles and detecting them with an ultrasensitive magnetic sensor array. MagArray Inc. presently occupies 5,000 square feet of lab space in a molecular sciences incubator facility, and has access to the Stanford Nanofabrication Facility on a fee-for-services basis. MagArray Inc. is financed by private investments and government grants, and has exclusive licenses of core intellectual properties developed at Stanford University as well as within MagArray.

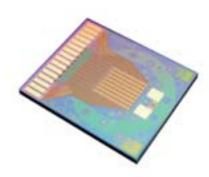
There is an evolving revolution in diagnostic medicine being driven by the availability of molecular diagnostic assays. This revolution will accelerate as biomarker panels are established for more and more diseases. Perhaps the most active area in cancer research is the search for biomarker panels specific to the different species of cancer, either for therapy prediction/ monitoring or for earlier diagnosis. When such panels are identified, the need for a high-sensitivity multiplexed assay will also explode. Such diagnostic assays will be necessary in the research stage as platforms for the establishment of the clinical efficacy for the biomarker panels, but the market will reach its peak size once the biomarker panels reach the clinical application stage. No presently available molecular diagnostic assay such as ELISA or Luminex meets the need of the marker panel application. The unique and remarkable capabilities of the MagArray assay system make it a prime candidate to facilitate

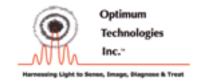
and underpin the revolution in diagnostic technology presently emerging in diagnostic medicine. MagArray Inc.'s vision is that we become a key assay platform supplier to the molecular diagnostics field. Our initial focus is on a cancer diagnostic assay for the research market and a cardiac assay for the clinical market.

MagArray Inc. has demonstrated the detection of proteins such as carcinoembryonic antigen (CEA) down to 0.01 pg/mL (Nature Medicine, Oct. 11, 2009) and troponin (Tn) down to 1 pg/mL concentrations. We have also demonstrated high sensitivity and selectivity in multiplex assays where 4-20 biomarkers are detected simultaneously (PNAS, Dec. 30, 2008). MagArray Inc. is actively developing both the bioassay chemistry and the actual hardware on which the measurements are carried out, including the giant magnetoresistive (GMR) sensor chip (Figure), the chip cartridge and the chip cartridge reader station. The GMR sensor chip features 64 sensors in an 8x8 array, which can be individually functionalized with different antibodies.

The leaders of the company are among the pioneers of magnetic biosensors and nanotechnology, with necessary knowhow and credentials in the practice of biochips:

- Dr. Shan X. Wang, Chief Scientist
- Dr. Robert L. White, President
- Dr. Sebastian J. Osterfeld, VP of Engineering
- Dr. Heng Yu, Director of Biochemistry
- Dr. Nader Pourmand, Cofounder and Director
- Dr. Ron Davis, Chair of Scientific Advisory Board
- Dr. Sam Gambhir, Stanford Medical School





Optimum Technologies, Inc. www.optimum-tech.com 68 West St. Southbridge, MA 01550 Randal Chinnock
Founder/CEO
Telephone: 508-765-8100 x204
rchinnock@optimum-tech.com

12:45 p.m. – 1:00 p.m. Devices

Clinical Needs - Improved minimally invasive products are needed to differentiate cancerous and non-cancerous tissues in vivo. The present standard of care is invasive, costly, and inefficient. In our targeted applications (bladder and gastrointestinal tract), there is no clinically accepted alternative to the technique that has been used for over 50 years: excisional biopsy and histo-pathological assessment of polyps or other suspicious lesions. These methods cause bleeding, pain, risk of organ perforation, and other complications. Due to the invasive nature of these existing techniques, only a few samples of tissue may be collected during a procedure, and the selection of sampling sites is based solely on visual appearance. Results are sometimes not available for days, causing unnecessary patient anxiety and delays in scheduling treatment. Lab samples can be mislabeled or lost, which can result in unnecessary treatments that include a full regimen of chemotherapy. A technique is needed that mitigates these risks, costs, morbidity, and limited sampling.

**Technology and Benefits** – With a flash of light, Optimum Technologies' (OTI's) minimally invasive technology

differentiates normal and malignant tissues. The system uses the technology of polarized elastic scattering spectroscopy (PESS). It therefore requires no indicator dyes, molecular markers, or other exogenous (foreign) agents, so no new FDA drug clearance is needed. This means faster time to market than many other methods currently

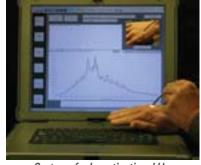
under development. Because it is a point measurement system rather than an imaging modality such as NMR, CT, OCT and ultrasound, PESS is simple, low cost, and easy to use with minimal training. The system will produce a probability of cancer for each reading. There are no complex images to interpret, and resultant inter-observer variations are eliminated. OTI holds 2 issued patents for PESS, has filed 2 provisionals, and has other patent applications in preparation. Regulatory and reimbursement strategies are defined.

**Business Opportunity** – Worldwide each year there are 356,000 new cases of bladder cancer, 410,000 new cases of esophageal cancer, and 940,000 new cases of colorectal cancer. PESS is capable of detecting carcinomas in all of these organ systems, as well as skin, mouth, brain, sinuses, lungs, and cervix. Ongoing clinical studies have demonstrated the potential of this "optical biopsy" technique to differentiate normal and diseased tissues with very high accuracies. The overall US markets for gastrointestinal devices exceeded \$1.2 billion in 2007. Driven in part by demand for minimally invasive devices to diagnose colorectal cancer, this market is expected to increase to over \$1.6 billion in 2011. Moreover, the use of instant diagnostic technologies such as PESS will produce a cost savings of over \$95 million just for the 1.6 million annual colonoscopies which will no longer require pathology workups in the lab. Most gastrointestinal endoscopy is performed in endoscopy suites in hospitals. There are ~6,000 hospitals in the U.S. and double that number abroad.

**Financial Overview** - OTI's business plan calls for cumulative sales in the first 5 years of \$1B. Much of this revenue will be comprised of disposable probes with gross margins in the range of 70% and pre-tax earnings in the range of 15-20% of revenues. OTI seeks funding to augment its NIH support. Funds

will be used to continue product development, conduct pivotal human studies, execute its regulatory and reimbursement strategies, and establish distribution partners. Initial products can be launched in less than 30 months.

**Company and Team** – OTI is a medical technology- and product-development



Systems for Investigational Use

company founded in 1994 that has assisted hundreds of companies commercialize new devices. OTI has been developing the PESS technology on its own using NIH and internal funding. Founder/CEO Randal Chinnock has 30 years of experience in the development and commercialization of electro-optical, opto-mechanical, and surgical devices and instrumentation. VP of R&D Fred Bargoot holds a Ph.D. in molecular physics and has 35 years of experience successfully developing and managing the development of products for medical device, industrial, biotechnology, clinical diagnostics, and food and dairy markets. Program Manager George Grubner holds an MS degree in Electrical Engineering from Harvard University and an MBA from Babson College, and has over 30 years of experience developing and commercializing electronic instrumentation systems encompassing hardware, electronics, firmware, and control architecture. Long-time collaborator Irving Bigio, Ph.D. is a professor of Biomedical Engineering and Computer and Electrical Engineering at Boston University and Director of the Biomedical Optics Laboratory at BU. He is a pioneer in the use of elastic scattering spectroscopy for optical cancer detection, and has been a key contributor to OTI's technology development efforts. Satish Singh, M.D. is conducting a clinical study in the colon using OTI hardware at Boston Medical Center. Louis Liou, M.D. is conducting a clinical study for OTI in the bladder at a Harvard affiliate hospital. Lev Perlman, Ph.D. is a collaborator at Beth Israel Deaconess Medical Center and is conducting a clinical study in the esophagus using OTI hardware.

PathfinderTherapeutics, Inc. ("PTI" or "the Company") is pioneering the development of 3 dimensional imaging and real time abdominal navigation to improve disease management, treatment planning and intra abdominal guidance. The Company has developed core image guided software and guidance system that improves the ability of the clinicians to identify the best course of treatment for a patient, enhance the ability to deliver that treatment, and measure the effectiveness of that treatment over time. The Company's initial focus is on liver cancer with products to include the kidney and pancreas to be released near term. Other key organs will be added to the product offering as well.

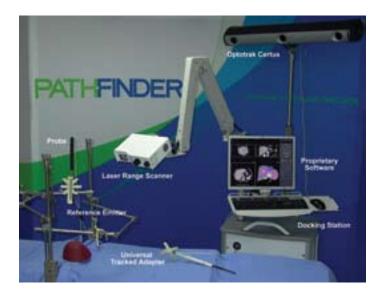
Specifically, the Company has developed an image based guidance platform consisting of imaging software for pretreatment – PlaniSight – and SurgiSight, an intra abdominal navigation system. PlaniSight and SurgiSight are FDA cleared for open liver resection and ablation procedures.

The PlaniSight planning module operates initially as a disease management platform, rapidly and automatically producing high quality images and volumetric data to enable clinicians to identify tumor locations and progression over time. Key data produced through this analysis enables physicians to assess the effectiveness of previous treatments and determine future courses of treatment. If the treatment solution is a surgical resection or ablation of a tumor, PlaniSight automatically creates 3D image segmentations of the liver, tumor, and vascular structure. The physician can then create a resection plane to optimize the surgical outcome. The software

### PATHFINDER

Pathfinder Therapeutics, Inc. www.pathsurg.com 2969 Armory Dr., Suite 100A Nashville, TN 37204

12:00 p.m. – 12:15 p.m. Devices Curtis "Skip" Goode President Telephone: 615-783-0094 skipg@pathsurg.com



automatically provides the physician the volume measurements of the total liver, functional liver, the resected and remnant portions of the liver.

The SurgiSight Navigation system enables real time guidance to accurately follow the pre-operative plan once in the OR environment. The objectives of a liver resection procedure is to remove the necessary volume of the organ to ensure the removal of the tumor and tumor cells while leaving as much healthy liver tissue as possible to enhance patient recovery and accelerate organ regeneration. The navigation system provides the surgeon with a tool to reach these objectives more effectively.

PTI is developing intra abdominal guidance systems for use in minimally invasive resection and ablation procedures for the liver, kidney, and pancreas. Our minimally invasive navigation system will provide the same benefits found in open resections and ablations. These applications will allow more patients to be treated more effectively than current treatments offered and will increase the utilization of the Company's products across physician specialties.

As PTI establishes intra abdominal guidance as a standard of care for minimally invasive and open resection and ablation procedures for the over 700,000 patients diagnosed annually with liver, kidney, and pancreatic cancer, the Company will be a prime target for acquisition. Medical device companies will see the improvement in outcomes of the ablation procedures where their products are utilized due to accurate placement of their devices. Current image guided companies focusing on rigid structures including skull, spine, and orthopedic joint will see the opportunity in this new burgeoning field of soft tissue guidance and realize the opportunity to add a vibrant market to supplant their maturing markets. It is the company's belief Covidien, Acculis, BSD Medical from the device industry and Medtronic, GE Medical, and Stryker from the image guided industry, to name a few, would have an interest in acquisition. Each has a history of acquiring companies and technology to enter new markets.



Progenra, Inc. www.progenra.com 271A Great Valley Parkway Malvern, PA 19355

Tauseef R Butt, Ph.D CEO Telephone: 610-644-6974 ext 301 butt@progenra.com

9:45 a.m. – 10:00 a.m. Therapeutics/*In vitro* Diagnostics

Progenra Inc is a leader in companies focusing on ubiquitin cell pathways, which have an essential role in a number of pathophysiologies. The company's mission is to discover new medicines addressing unmet medical needs. Progenra's drug discovery platform and unique profiling capacity have identified first in class selective inhibitors of critical ubiquitin pathway enzymes associated with cancer, osteoporosis, and other debilitating diseases. Among these is a highly promising anticancer compound, currently in development for the oncology market.

Company and the team: Progenra is a seven year old biotechnology company driven partly by private investments. The company has built state of the art laboratory facilities in the Great Valley Corporate Center, a biotech hub of the western Philadelphia suburbs. The Progenra team is composed of seasoned management, formerly from GSK. Dr. Tauseef Butt, President and CEO of Progenra, has raised several million dollars and brought numerous technologies and products to the market. Dr. Michael Mattern, COO of Progenra, has 20 years of experience at GSK in anticancer drug development. In addition, Progenra is honored to have a highly distinguished Scientific Advisory Board.

Competitive Edge: Progenra is at the forefront in the discovery of innovative medicines modifying the ubiquitin pathway: Its research program is enabled by novel targets, superior platform technologies, and in-house medicinal chemistry facilities. Progenra's competitive advantage is its single minded focus on the ubiquitin pathway, for example, the company has expressed, purified and characterized all the enzymes of the human deubiquitylase family (~100 members). Progenra is thus set up to reject non-selective compounds early in the development cycle, thereby reducing the risk of failure of compounds in clinical

stages. The most advanced program at Progenra is a first in class unique de-ubiquitylase targeting compound.

Market Opportunity: The ubiquitin pathway affords numerous novel therapeutic targets. Progenra pursues a discovery program that has created several opportunities to establish partnerships with other companies. Progenra is interested in discussing: 1) discovery collaborations with companies interested in exploring their internal compound libraries and 2) co-development partnerships with companies seeking the power of Progenra's repertoire of platforms to enable the selection of chemical entities most likely to succeed in the clinic. The company's most advanced program has identified a deubiquitylase inhibitor currently in pre-clinical development. This molecule is first in its class of drugs with a unique anticancer mechanism. Progenra is actively seeking investment and partnership opportunities centered on this molecule.



Syntrix Biosystems, Inc. www.syntrixbio.com 215 Clay Street NW, Suite B-5 Auburn, WA 98001

John A. Zebala, MD, PhD CEO

Telephone: 253-833-8009 izebala@syntrixbio.com

9:15 a.m. – 9:30 a.m. Therapeutics

Company: Syntrix Biosystems, Inc. (Auburn, WA) is a privately held pharmaceutical company that opportunistically identifies low- to moderate-risk small-molecule development opportunities that address high-value unmet needs in therapeutic markets that include oncology, rheumatology, dermatology and pulmonary disease. The company's strategy is to rapidly move its pipeline of therapeutic candidates through clinical and regulatory development to maximize deal valuation at the time of partnering with established multinational pharmaceutical companies. Since its inception, Syntrix Biosystems has been awarded over \$15 million in non-dilutive financing from the National Institutes of Health in support of its development efforts.

**Pipeline:** The company's preclinical and clinical-stage pipeline of oral small-molecule candidates include: (1) *rac*-aminopterin (a new antifolate aimed at capturing key high-value markets in rheumatology and dermatology, highlighted below), (2) the neutrophil chemotaxis inhibitor SX576 aimed at the COPD and other inflammatory disease markets (SX576 allosterically inhibits the G-protein coupled receptor CXCR2), and (3) novel formulations and analogues of a non-opioid analgesic aimed at capturing the existing tramadol market (there were 18,526,000 tramadol prescriptions in 2007 and \$281 million in retail sales).

Highlighted Pipeline Investment Opportunity: Given the critical dual role that antifolate therapy with the mainstay methotrexate (MTX) plays in *both* oncology and inflammatory disorders, there has been intense interest in developing improved antifolates (there are ~4,000,000 MTX prescriptions per year, mainly for arthritis and psoriasis). In oncology, the recent approvals of

Therapeutic	Aminopterin tablets, 0.25 mg – 1.0 mg, oral		
Indications	PTCL and other oncology / rheumatoid arthritis / psoriasis		
Development Phase	Phase 2 oncology / Phase 1-2 inflammation		
U. S. Patent Term*	Until 2030 for all indications		
Hatch/Waxman Exclusivity	Statutory NCE entitled to 5 years new product exclusivity		
Market Positions	Better MTX, oral alternative to biologic (e.g. anti-TNF) therapy		
U. S. Market (Oncology / RA / Psoriasis)	\$1.1 - \$2.6B (\$140 - \$280M / \$700 - \$1500M / \$300 - \$800M)		
Business Opportunity Sought	Development Partner / Licensing / Investment		
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Table 1. Racemic Aminopterin (rac AMT) fast fact summary.

pralatrexate (Folotyn™, Allos Therapeutics) for peripheral T cell lymphoma (PTCL) and pemetrexed (Alimta®, Eli Lilly & Co.) for mesothelioma and non-small cell lung cancer (NSCLC) provide vivid evidence that interest in improved antifolates in oncology is brisk.

In the treatment of inflammatory disorders, 87% of MTX users have adverse side effects and 30% have to withdraw within a year due to either its toxicity or lack of efficacy (i.e. MTX "failures"). Patients with rheumatoid arthritis (RA) and psoriasis who fail standard therapy with MTX are additionally treated with biologic (anti-TNF) drugs such as Enbrel®, Remicade® and Humira®. The cost of biologic therapy is approximately \$40,000 per year for each patient, and total biologic sales for RA and psoriasis in 2006 were over \$10 billion.

There is therefore an urgent and high-value unmet opportunity in the current pharmacopeia for a new antifolate that provides superior clinical efficacy and less toxicity than MTX in oncology and inflammatory indications, and that is priced between MTX and biologics.

Racemic-aminopterin (rac-AMT) is a proprietary antifolate being developed by Syntrix Biosystems, Inc. as a "better methotrexate" that is aimed at meeting these unmet needs in oncology, RA and psoriasis. Laboratory and clinical data suggest that rac-AMT is more effective than MTX in oncology and inflammation and causes fewer side effects. For those with RA and psoriasis who have failed therapy with MTX, rac-AMT thus offers a therapeutic value proposition similar to that of biologics but at a lower cost, and with the added benefit of convenient once-weekly oral dosing. A superior and better tolerated oral



therapy with otherwise identical prescribing to MTX would be adopted quickly by clinicians. The domestic *rac*-AMT market is estimated at \$1.1 to \$2.6 billion.

#### VISUALASE, INC.

Visualase, Inc. www.visualaseinc.com 8058 El Rio St. Houston, TX 77054

12:30 p.m. – 12:45 p.m. Devices



Telephone: 713-275-2063 bhoffman@visualaseinc.com

Business / General: The business of Visualase is to develop, manufacture, and sell minimally invasive laser ablation systems and their related disposables, for the purpose of destroying tumors and other soft tissue. The Visualase technology is proprietary, strongly IP protected, and game changing. The Visualase system is fully developed, already FDA cleared with a broad indications, and is currently being used commercially in the US. Visualase, because of the unprecedented level of control and precision offered by the technology, faces several large patient populations who have no options, in markets that have never been accessed by previous ablative technologies. Excellent reimbursement exists and average sales price will reflect this fact. Manufacturing, completed at our Houston facility is simple, scalable, and low cost leading to high gross margins. Disposables will represent > 80% of the total revenue stream.

**Technology & Market:** The Visualase system allows visualization, control, and monitoring of laser ablation procedures in real time, as well as modeling of the of the kill zone while it is being created. The sharp demarcation of dead vs. unharmed tissue (<1mm) associated with laser, combined with the ability to monitor and control the to sub-millimeter levels of accuracy, offers a level of precision never before attained with ablative therapies. Visualase is actively pursuing applications in brain tumors, focal (tumor specific) prostate cancer, and epilepsy. The Visualase system is a platform

technology facing several large markets (as shown in the table) in which there are limited or poor patient options, poor or no competition, aggressive physician call points and high reimbursement.



#### **Key Highlights:**

- Proven platform technology that solves unmet clinical need in multiple markets
- Human clinical study on brain tumors completed, published in peer reviewed journal Neurosurgery
- Patients currently being treated and enrolled in clinical protocols for prostate cancer.
- Low technical and regulatory risk: all products FDA 510(k) cleared for marketing in the US
- \$3.5M Series A financing recently completed through Toronto based Eventi Capital Partners
- Patented technology: five patents granted, eleven pending, >200,000 lines of proprietary software

#### Visualase Team:

**Bill Hoffman, CEO** - Bill Hoffman has extensive commercial experience with early stage medical device companies, especially those focused on novel and potentially disruptive technologies. Bill's previous positions include Chief Operating Officer at Rubicor Medical which was focused on image guided percutaneous lumpectomy and a novel hand held breast biopsy device. Prior to that, Bill was VP of Sales at FoxHollow Inc., building from scratch a team of 250 sales professionals, and driving arguably the fastest revenue ramp in the medical device history: from \$0 in O2 2003 to \$138M in calendar year 2005. Bill also served as Director of Sales for RITA Medical Systems, the first volumetric RF ablation company in the US and helped execute a plan which resulted in a successful IPO in 2000.

Ashok Gowda Ph.D., Founder and COO – Dr. Gowda has over 10 years experience in directing medical device technology development and has contributed to the Visualase effort on both the scientific and management fronts. Dr. Gowda led the company through the development phases and through regulatory approvals including the initial human clinical studies. Dr. Gowda received his B.E. degree in Biomedical Engineering from Vanderbilt University in 1991 and the M.S. and Ph.D. degrees in Bioengineering from Texas A&M University in 1998.

Roger McNichols Ph.D., Founder and CTO - Dr. McNichols is responsible for overseeing all aspects of research and development of the Visualase technology. Dr. McNichols has extensive experience in biomedical optics, software, and magnetic resonance technology. Dr. McNichols received a B.S. in Electrical Engineering from the Ohio State University in 1992 and a Ph.D. in Biomedical Engineering from Texas A&M University in 1998.



Zacharon www.zacharon.com 5626 Oberlin Drive San Diego, CA 92121 Robin Jackman
President & CEO
Telephone: 858-768-7828
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10:00 a.m. – 10:15 a.m. Therapeutics/*In vitro* Diagnostics

#### Introduction

Zacharon is leveraging innovative drug discovery technology to enable, for the first time, development of small molecule drugs targeting glycan biosynthesis. Glycans are the carbohydrate chains of glycoproteins, proteoglycans, and glycolipids and encompass a broad selection of specific and potent drug targets. Our most advanced programs are in lead optimization for oncology and lysosomal storage disease. The lysosomal storage disease market currently exceeds \$3B and is characterized by strong growth rates, attractive operating margins, and limited competition.

### Glycans: An Attractive But Historically Challenging Target

Based on strong preclinical evidence, targeting discrete points in glycan biosynthesis represents a highly specific and potent therapeutic strategy for cancer, lysosomal storage disease, inflammatory disease, and other applications. However, several key challenges have until now precluded the development of drugs targeting glycan biosynthesis:

Program (Glycan Target)	Applications	Screen	Hits	Hit-to- Lead	Lead Opt.	Pre-clinical Studies	Clinical Studies
Heparan Sulfate Therapeutic	Lysosomal Storage Disease     Oncology	•					
Ganglioside Therapeutic	Gangliosidosis (Tay-Sachs, etc.)     Neuroblastoma, others	•					
O-Linked Therapeutic	• Inflammation • Metastasis	•	•				
N-Linked Therapeutic	Oncology     Viral Infections (HIV)	•	•				
Sensi-Pro Assay	Clinical diagnostic for lysosomal storage diseases		l studies cor alidation stu	nplete dies ongoing	ı		

- 1. The biosynthetic pathway, structure, and resulting function of glycans were not well understood
- 2. Methods for analyzing the highly complex glycan structures, central to glycan-driven pathology, were not available
- 3. Effective high-throughput small molecule screening technology did not exist

### Zacharon's Competitive Advantage: Unique Technology and Strategy Enable a New Class of Therapeutics

To unlock this potential, over the past 5 years Zacharon has created breakthrough assay technologies integrating cell-based high-throughput screening with highly sensitive glycan structural analysis tools. Combined with recent advances in the understanding of glycan biosynthesis and function, Zacharon's technology provides a powerful and proprietary platform for novel small molecule drug discovery of an entire new class of therapeutics. By coupling this drug discovery engine with traditional downstream small molecule drug development, Zacharon is creating a broad pipeline of novel therapeutics for many diseases where glycans are strongly implicated in disease pathogenesis.

### **Funding and Intellectual Property**

Since its inception in 2004, Zacharon has been awarded nearly \$3M in SBIR grants and recently received Series A funding from Avalon Ventures. The company has executed an intellectual property strategy involving patent filings and trade secrets surrounding its assay technologies, glycan targeting approach, and small molecule drugs.

### **Progress and Upcoming Milestones**

Zacharon has completed high-throughput screening and has initiated medicinal chemistry and other preclinical activities. Proof of concept has been demonstrated in oncology and lysosomal storage disease models for the Heparan Sulfate program. Key upcoming milestones are shown below.

Milestone	Timing
in vivo efficacy data (Heparan Sulfate)	Q2 2010
Initiation of lead optimization (Ganglioside)	Q1 2010
Clinical validation of Sensi-Pro Assay	Q4 2009

\* Note: Reference to any specific cancer statement and commercial products, process, service, manufacturer, and/or company, does not constitute an endorsement or recommendation by the National Cancer Institute (NCI), the NCI's Small Business Innovation Research (SBIR) & Small Business Technology Transfer (STTR) Programs, or any other portion of the U.S. Government.

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